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Bioterrorism Act 2002

We are pleased to submit herewith the official comments outlining Malaysia's concerns on the draft regulations intended to implement the Bioterrorism Act 2002 as well as to seek further clarifications from the FDA on the specific issues highlighted in the accompanying Annex.

It is our hope that the implementing agencies of the Bioterrorism Act 2002, particularly the FDA and the Department of Health and Human Services will address the concerns and questions raised by Malaysia.

The Embassy of Malaysia is appreciative of the opportunity given to Malaysia and the international community in conveying our specific comments. Malaysia welcomes any future consultations and discussions with the FDA on this very important Act.

Thank you.


Seng Foo Wong
Minister- Counsellor (Economics)
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Annex

Malaysia would like to register the following reservations and seek further clarification on the following issues.

1. Section 303 (Administrative Detention)

Malaysia is concerned that the detention period (not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary) will affect the shelf life of the articles. Malaysia is especially concerned on the matter of perishables including seafood products, such as prawns.

Further clarification is sought on the phrase 'expedited basis' mentioned as a note in Section 303, paragraph (2). Does this involve a shorter time period and by how many days?

2. Section 304 (Debarment For Repeated or Serious Food Import Violations)

List of debarred US importers should be made available. This will keep Malaysian exporters informed on the valid importers/agents so as to avoid costly detention of shipments.

3. Section 305 (Registration of Food Facilities)

Malaysia would like to state the reservation that the registration requirement for every level of the production process (even involving sub-contractors) is tedious, time consuming and burdensome.

Special concern is raised by smaller companies in that implementing Section 303, especially with regards to electronic filing, may require additional resources such as hiring clerical personnel to use internet facilities.

Malaysia is concerned that resultant additional storage and transport will further increase costs.

Malaysia seeks further clarification on the registration procedures and mechanism. **Malaysia proposes that a Guideline i.e. Standard Operating Procedure for Exporters be produced to aid Malaysian and other foreign exporters.**

Malaysia seeks clarification on whether there is a need to register middlemen involved along the line from the initial production process to the final consumption of the end product in the United States.

Malaysia also seeks clarification whether facilities already registered under a different Act is required to register under Section 305. For certain categories of food such as low acid canned food, some Malaysian facilities have to file their process in detail with the FDA prior to importation into the US. The purpose to determine if the article is safe under the declared processing conditions is deemed onerous.

Note: For first time registration, Malaysian companies are required to fill Form 2541 for premise registration and US FDA will revert to them a Food Canning Establishment No. (FCE No.). They are subsequently required to file all products that are exported into the US using another form: Form 2541a or 2541c (depending on product).

4. Section 306 (Maintenance and Inspection of Records for Foods)

Malaysia seeks further clarification on the term 'immediate previous sources' which may be in possible conflict with Section 305. This pertains especially to farms, which is exempted from list of facilities requiring registration (Section 305). Malaysia would like to make known that for some production activities (i.e. aquaculture sector) immediate previous sources are farms.

5. Section 307 (Prior Notice of Imported Food Shipments)

Malaysia seeks further clarification on procedures involved in prior notification to help foreign exporters.

6. Section 322 (Requirement of Additional Information Regarding Import Components Intended for Use in Export Products)

Malaysia is concerned that the Act does not state the type of analysis required to determine import components and that Malaysia may not have adequate and appropriate facilities to undertake the necessary testing.

Malaysia is concerned that the requirement of certificate of analysis may result in additional costs for the exporter.